

## NEWS RELEASE



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**Department of Commerce and Insurance  
Commissioner Leslie Newman**

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### **TENNESSEE, 32 STATES, REACH LANDMARK \$62 MILLION SETTLEMENT WITH ELI LILLY RESOLVING IMPROPER MARKETING CLAIMS**

Attorney General Bob Cooper and Division of Consumer Affairs Director Mary Clement announced today that Tennessee along with Attorneys General from 32 states reached a record \$62 million settlement with Eli Lilly and Company arising from alleged improper marketing of the antipsychotic drug Zyprexa. It is the largest ever multi-state consumer protection-based pharmaceutical settlement, with Tennessee's share estimated at \$1,570,831.

The states alleged that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses and for failing to adequately disclose to healthcare providers the drug's potentially dangerous side effects. Following a 1.5-year investigation, Eli Lilly agreed to change how it markets Zyprexa and to cease promoting its "off-label" uses, which are not approved by the U.S. Food and Drug Administration (FDA). The case comes on the heels of the May 2008, \$58 million agreement with Merck regarding its product Vioxx.

"We are pleased to announce the resolution of this investigation into the off-label promotion of this drug," Attorney General Cooper said. "We hope other companies will think twice before potentially endangering patients' health for their own profit."

Zyprexa is the brand name for the prescription drug olanzapine. The drug was first marketed for use in adults with schizophrenia in 1996. Since then, the FDA has approved Zyprexa for the treatment of acute mixed or manic episodes of bipolar I disorder and for maintenance treatment of bipolar disorder. Zyprexa belongs to a class of drugs traditionally used to treat schizophrenia and commonly referred to as "atypical antipsychotics." When these drugs were first introduced to the market in the 1990s, experts thought that atypical antipsychotics would be less likely to produce symptoms similar to those seen in Parkinson's disease (extrapyramidal symptoms), and motion disorders (tardive dyskinesia), and therefore could be used in long-term treatment of schizophrenia. While these drugs may reduce the risk of these symptoms associated with first-generation antipsychotics, they also produce dangerous side effects, including weight gain,

hyperglycemia, diabetes, cardiovascular complications, an increased risk of mortality in elderly patients with dementia and other severe conditions. Zyprexa has been associated with a high risk of weight gain, hyperglycemia, and diabetes.

In 2001, Eli Lilly began an aggressive marketing campaign called “Viva Zyprexa!” As part of that campaign, the company marketed Zyprexa for a number of off-label uses. For example, it marketed Zyprexa for pediatric use, for use at high dosage levels, for the treatment of symptoms rather than diagnosed conditions, and in the elderly for the treatment and/or chemical restraint of patients suffering from dementia. While a physician is allowed to prescribe drugs for off-label uses, law prohibits pharmaceutical manufacturers from marketing their products for off-label uses.

The settlement mandates that for a six year time period extending beyond the patent term for Zyprexa, Eli Lilly shall (in addition to other requirements):

- \*Refrain from making any false, misleading or deceptive claims regarding Zyprexa or promote it for any off-label purposes;
- \*Require its medical staff, rather than its marketing staff, to have ultimate responsibility for developing and approving the medical content for all medical letters and medical references regarding Zyprexa, including those that may describe off-label information;
- \*Provide specific, accurate, objective and scientifically balanced information to healthcare providers regarding Zyprexa;
- \*Disclose information about grants, including continued medical education on its Web site ([www.lillygrantoffice.com](http://www.lillygrantoffice.com)), for at least two years and maintain the information for five years;
- \*Contractually require continuing medical education providers to disclose Eli Lilly’s financial support of their programs and any financial relationship with faculty and speakers;
- \*Provide each Attorney General in the agreement a list of health care provider promotional speakers and consultants who were paid more than \$100 for promotional speaking and/or consulting by Eli Lilly;
- \*Only provide product samples of Zyprexa to a health care provider whose clinical practice is consistent with the product’s current labeling; and
- \*Register clinical trials and submit results as required by federal law.

The State’s Complaint and Agreed Final Judgment may be viewed by going online to [www.tn.gov/attorneygeneral/](http://www.tn.gov/attorneygeneral/). If consumers have complaints regarding prescription drug advertisements or any other deceptive conduct, they may file go online to <http://www.state.tn.us/consumer/> or call the Division of Consumer Affairs at (615) 741-4737 or toll-free in Tennessee at 1 (800) 342-8385.